Merit Medical Systems, Inc.
Merit Prelude™ Sheath Introducer
Special [510(k)] PREMARKET NOTIFICATION
CONFIDENTIAL

Attachment 4

JUN 2 1 2007

510(k) Summary

SAFETY AND EFFECTIVENESS SUMMARY

This information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by Name/Address:	Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan, Utah 84095
Establishment Registration Number:	1721504
Primary Contact Person:	Jerrie Hendrickson Regulatory Affairs Specialist II Telephone: (801) 208-4119 Fax: (801) 253-6918 Email: **jhendri@merit.com**
Alternate Contact Person:	Stephanie A. Erskine Vice President Corporate Regulatory Affairs Telephone: (801) 208-4349 Fax: (801) 253-6967 Email: serskine@merit.com
Date Summary Prepared:	January 16, 2007
Trade Name:	Prelude™ Sheath Introducer
Common Name:	Vessel Dilator for Percutaneous Catheterization
Classification Name	Vessel Dilator for Percutaneous Catheterization, Class II, Product Code DRE (per 21 CFR 870.1310)
Predicate Device	Prelude™ Sheath Introducer (K050962), manufactured by Merit Medical Systems, Inc.

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Device Description:	Merit Medical System's Prelude™ Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath is equipped with a sideport attached to a segment of extension tubing terminating in a 3-way stopcock. The sheath hub contains an integral hemostasis valve and suture ring. The device is marketed with and without an appropriately sized guide wire and/ or access needle.
Intended Use	The Merit Prelude™ Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/ or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.
Technology Comparison	The modified device has the identical intended use and employs the same fundamental technology as the predicate device. Additional sizes have been added, minor changes in materials have been made, and the configuration of the dilator tip has been modified to accept smaller size guide wires. In addition, some kits containing the Prelude™ are now marketed with appropriately sized guide wires and access needles.
Performance Testing	Verification and Validation Studies, as identified in the Clinical Risk Assessment, were completed and demonstrated that the modified devices met all of their pre-determined acceptance criteria.

Summary of Substantial Equivalence

Based on:

- Merit's conformance with Design Control requirements,
- Analyses of Risks associated with the Modified Device; and
- Results of Verification and Validation tests identified in the Risk Analyses demonstrating that predetermined acceptance criteria have been met:

the modified devices are as safe and effective as, and perform as well as, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2007

Ms. Jerrie Hendrickson
Regulatory Affairs Specialist
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

Re: K070159
Trade/Device Name: Prelude™ Sheath Introducer
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catherization
Regulatory Class: Class II
Product Code: DRE
Dated: May 21, 2007
Received: May 23, 2007

Dear Ms. Hendrickson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 2

Indications for Use Statement

510(k) Number (if known): K070159

Device Name: Merit Prelude™ Sheath Introducer

Indications for Use:

The Merit Prelude™ Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 901 Subpart D) (21 CFR 807 Subpart O)

(PLEASE DO NOT WRITE BELOW THIS LINE -
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070159